K000695

MAR 1 6 2000

Section 2:
510(k) Summary
Per 21 CFR Part 807.92.

GE Medical Systems

General Electric Company
P.O. Box 414, Milwaukee, WI 53201

Section a):

1. Submitter: GE Medical Systems
PO Box 414
Milwaukee, WI 53201

Contact Person: Allen Schuh,
Manager, Safety and Regulatory Engineering
Telephone: 414-647-4385, Fax: 414-647-4090

Date Prepared: January 26, 2000

2. Device Name: GE Dolphin Diagnostic Ultrasound System.
Ultrasonic Pulsed Doppler Imaging System, 21 CFR 892.1550, 90-IYN

3. Marketed Device: GE Dolphin is substantially equivalent to the GE Vingmed System FiVe system, 510(k) Number K963315, a device currently in commercial distribution.

4. Device Description: The GE Dolphin Ultrasound System consists of a mobile console approximately 625 mm wide, 1125 mm deep and 1350 mm high with digital beam former and assorted electronic array transducers. The user interface consists of a keyboard control panel and color video display monitor. It is network accessible and has integrated on-board image storage and hard-copy devices.

5. Indications for Use: The GE Dolphin system is a general purpose ultrasound system specialized for cardiac imaging. Specific clinical uses include cardiac (adult and pediatric); transesophageal; abdominal including GYN and urology; fetal; intraoperative; peripheral vascular; pediatric; small organ including breast, testes, thyroid; adult and neonatal cephalic; and musculo-skeletal (conventional and superficial).

6. Comparison with Predicate Device: The Dolphin diagnostic ultrasound system is of comparable type and substantially equivalent to the device identified in Section a) 3 above. It has the same technological characteristics, is comparable in key safety and effectiveness features, uses similar design, construction, and materials, and has the same intended uses, transducers and operating modes as the predicate devices.

Section b):

1. Non-clinical Tests: The device has been evaluated for acoustic output, biocompatibility, and thermal, electrical and mechanical safety, and has been found to conform with applicable medical device safety standards.

2. Clinical Tests: None required.

3. Conclusion: Intended uses and other key features are consistent with traditional clinical practice, FDA guidelines, and established methods of patient examination. The design and development process of the manufacturer conforms with 21 CFR 820 Quality System Regulation and ISO 9001 & EN 46001 quality system standards for medical device manufacturers. The product is designed to conform with applicable medical device safety standards and compliance is verified through independent evaluation with ongoing production surveillance. Diagnostic ultrasound has accumulated a long history of safe and effective performance. Therefore, it is the opinion of GE Medical Systems that the GE Dolphin Ultrasound System is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 16 2000

GE Medical Systems
C/O Carole Stamp
TUV Product Services
Suite 104
1775 Old Highway 8 NW
New Brighton, MN 55112-1892

Re: K000695
GE Dolphin Diagnostic Ultrasound System
Regulatory Class: II/21 CFR 892.1560, 21 CFR 892.1550 and 21 CFR 892.1570
Procode Code: 90 IYO, 90 IYN and 90 ITX
Dated: February 26, 2000
Received: March 1, 2000

Dear Mr. Shuh:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the GE Dolphin Diagnostic Ultrasonic Engineering, as described in your premarket notification:

Transducer Model Numbers

358C, 739L, 3S, 7S, PAMTEE, CW2

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note*: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Robert A. Phillips, Ph.D. at (301) 594-1212.

Sincerely yours,

for David A. Lehman

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

Diagnostic Ultrasound Indications for Use Form

GE Dolphin Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N	N	N	N	N	N		N	N
Abdominal		N	N	N	N	N	N		N	N
Intraoperative (specify)		N	N	N		N	N		N	
Intraoperative Neurological										
Pediatric		N	N	N	N	N	N		N	N
Small Organ (specify)		N	N	N		N	N		N	
Neonatal Cephalic		N	N	N	N	N	N		N	N
Adult Cephalic		N	N	N	N	N	N		N	N
Cardiac		N	N	N	N	N	N		N	N
Transesophageal		N	N	N	N	N	N		N	N
Transrectal										
Transvaginal										
Transuretheral										
Intravascular										
Peripheral Vascular		N	N	N	N	N	N		N	
Laparoscopic										
Musculo-skeletal Conventional		N	N	N		N	N		N	
Musculo-skeletal Superficial		N	N	N		N	N		N	
Other (specify)		N	N	N	N	N	N		N	N

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Cardiac is Adult and Pediatric. Small organ includes breast, testes, thyroid.

Combined modes are B/M, B/PWD, B/CWD, B/Color/PWD, B/Amplitude/PWD.

Intraoperative includes abdominal, thoracic, and vascular. Other use includes Urology and GYN.

Other mode includes Harmonic Imaging.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription User (Per 21 CFR 801.109) ✓

David A. Lyon
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K000695

Diagnostic Ultrasound Indications for Use Form

GE Dolphin with 358c Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N	N	N		N	N		N	
Abdominal		N	N	N		N	N		N	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N		N	N		N	
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transuretheral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Other use includes GYN and Urology.

Combined modes are B/M, B/PWD, B/CWD, B/Color/PWD, B/Amplitude/PWD

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

David A. Seyam
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K000695

Diagnostic Ultrasound Indications for Use Form

GE Dolphin with 739L Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N	N	N		N	N		N	
Abdominal										
Intraoperative (specify)		N	N	N		N	N		N	
Intraoperative Neurological										
Pediatric		N	N	N		N	N		N	
Small Organ (specify)		N	N	N		N	N		N	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transuretheral										
Intravascular										
Peripheral Vascular		N	N	N		N	N		N	
Laparoscopic										
Musculo-skeletal Conventional		N	N	N		N	N		N	
Musculo-skeletal Superficial		N	N	N		N	N		N	
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Small organ includes breast, testes, thyroid.

Combined modes are B/M, B/PWD, B/Color/PWD, B/Amplitude/PWD

Intraoperative includes abdominal, thoracic, and vascular.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

David G. Hegyum
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K000695

Diagnostic Ultrasound Indications for Use Form

GE Dolphin with 3S Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N	N	N	N	N	N		N	N
Abdominal		N	N	N	N	N	N		N	N
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N	N	N	N		N	N
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic		N	N	N	N	N	N		N	N
Cardiac		N	N	N	N	N	N		N	N
Transesophageal										
Transrectal										
Transvaginal										
Transuretheral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)		N	N	N	N	N	N		N	N

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Cardiac is Adult and Pediatric. Other use includes Urology and GYN.

Combined modes are B/M, B/PWD, B/CWD, B/Color/PWD, B/Amplitude/PWD

Other mode includes Harmonic Imaging

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

David G. Hoyer
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K000695

Diagnostic Ultrasound Indications for Use Form

GE Dolphin with 7S Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal		N	N	N	N	N	N		N	N
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N	N	N	N		N	N
Small Organ (specify)										
Neonatal Cephalic		N	N	N	N	N	N		N	N
Adult Cephalic										
Cardiac		N	N	N	N	N	N		N	N
Transesophageal										
Transrectal										
Transvaginal										
Transuretheral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)		N	N	N	N	N	N		N	N

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Cardiac is Adult and Pediatric. Other includes GYN and Neurology

Combined modes are B/M, B/PWD, B/CWD, B/Color/PWD, B/Amplitude/PWD

Other mode includes Harmonic Imaging.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

David A. Segura
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K000695

Diagnostic Ultrasound Indications for Use Form

GE Dolphin with PAMTEE Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		N	N	N	N	N	N		N	N
Transesophageal		N	N	N	N	N	N		N	N
Transrectal										
Transvaginal										
Transuretheral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Cardiac is Adult. Other mode includes Harmonic Imaging.

Combined modes are B/M, B/PWD, B/CWD, B/Color/PWD, B/Amplitude/PWD

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

David G. Hegarty
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K000695

Diagnostic Ultrasound Indications for Use Form

GE Dolphin with CW2 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac				N	N					
Transesophageal										
Transrectal										
Transvaginal										
Transuretheral										
Intravascular										
Peripheral Vascular				N	N					
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Cardiac is Adult and Pediatric.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

David G. Hyams
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K000695